

Remarks

Claims 1-12 are pending in the application. Claims 13-15 have been cancelled.

Rejection under 35 U.S.C. § 102

Claims 13-15 have been cancelled. Therefore, the rejection of claims 13-15 under 35 U.S.C. § 102 is now moot.

Rejections Under 35 U.S.C. § 103

Claims 1, 2, 4, 6, 7, 11 and 12 stand rejected as obvious under 35 U.S.C. § 103(a) over Plattner, *et al.* (U.S. 4,219,497) in view of Furatu (EP 0 041 366), Morris, *et al.* (U.S. 4,314,987) and Akhavan-Tafti, *et al.* (U.S. 6,068,979). Applicants respectfully disagree with the rejection.

The Examiner recognizes that Plattner, *et al.* does not teach conducting the measurement, in the same sample volume, of total AT-III activity in the presence of heparin and AT activity in the absence of heparin. The Examiner finds that despite Plattner, *et al.*'s failure to teach this aspect of the invention, the invention would have been obvious in light of Futura, Morris, *et al.*, and Akhavan-Tafti, *et al.* These references, however, do not render the invention obvious because they would not lead the skilled artisan to the present invention. The references teach the measurement of different analytes with different reagents. None of the references teach sequential detection of the same analyte as presently claimed. Moreover, as the Examiner correctly notes, that none of the three references relate to the determination of AT-III.

For example, Furatu teaches the detection of several different analytes using distinct enzyme reactions. Furatu, therefore, does not teach the detection of the same analyte in a sequential reaction as presently claimed.

Similarly, Morris, *et al.* teaches the detection of various analytes by using different, sequentially-added detection reagents. The results of the second assay in Morris are dependent

upon the results of the first assay. Specifically, the second analysis step using DNA antibodies depends upon the use of antibodies directed against cell nuclei in the first analysis. This is completely different from the present invention where the results of the second determination of the interaction between AT and the AT binding partner is completely independent of the first determination of the interaction of AT binding partner and inferring substances.

With regard to Akhavan-Tafti, *et al.*, this reference teaches methods for the sequential detection of various analytes (labeled DNA molecules) that are different from each other. The multiple detections are carried out using different reagents.

The Examiner finds that the combination of references renders obvious the sequential measurement of thrombin activity in the same reaction mixture. According to the Examiner, one would have been motivated to perform measurements sequentially on a single sample in order to minimize the amount of sample required, to save time, reagents and materials, to simplify protocols and to reduce errors. The error with the Examiner's analysis is that this motivation would not have lead a skilled artisan to combine the references as the Examiner has done. The motivation cited by the Examiner is no more than a conclusory wish list for every commercial assay. "[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." (*In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006) cited with approval in *KSR Int'l v. Teleflex Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007)).

As noted above, none of the secondary references cited by the Examiner relate to the determination of AT. Neither do any of the references, including Plattner, teach the sequential detection of the same analyte in a single sample. The Examiner has not articulated any pertinent and specific reasoning that would lead one of skill in the art to determine AT by sequentially

detecting and AT binding partner in the same sample. Such reasoning is required, even under the new *KSR* standard. *Ex Parte Erkey et al*, Board of Patent Appeals and Interferences, Appeal 20071375, Decided May 11, 2007 (“We determine that the Examiner has not provided a sufficient reason or explicit analysis of why the disclosures of the references should be combined.”)

Accordingly, the combination of references does not render obvious the presently claimed invention. Therefore, Applicants respectfully request that the rejection of claims 1, 2, 4, 6, 7, 11 and 12 under 35 U.S.C. § 103 be withdrawn.

Claims 8-9 stand rejected as obvious under 35 U.S.C. § 103(a) over Plattner, *et al.* in view of Furatu, Morris, *et al.* and Akhavan-Tafti, *et al.*, and further in view of Exner (U.S. 6,051,434). Applicants respectfully disagree with the rejection because Exner does not address the lack of obviousness of claim 1 as a result of the combination of Plattner, *et al.* Furatu, Morris, *et al.* and Akhavan-Tafti as noted above. Accordingly, the combination of Plattner, *et al.* Furatu, Morris, *et al.*, Akhavan-Tafti, and Exner can not render obvious claims 8 and 9, which depend from claim 1. Therefore, Applicants request that the rejection of claims 8-9 under 35 U.S.C. § 103 be withdrawn.

Claim 10 stands rejected as obvious under 35 U.S.C. § 103(a) over Plattner, *et al.* in view of Furatu, Morris, *et al.* and Akhavan-Tafti, and further in view of Nesheim, *et al.* (U.S. 4,219,497). Applicants respectfully disagree with the rejection because Nesheim, *et al.* does not address the failure of the combination of Plattner, *et al.*, Furatu, Morris, *et al.* and Akhavan-Tafti, and Nesheim, *et al.* to render claim 1 obvious as noted above. Accordingly, the combination of Plattner, *et al.* Furatu, Morris, *et al.*, Akhavan-Tafti, and Nesheim, *et al.* can not render obvious

claim 10, which depends from claim 1. Therefore, Applicants request that the rejection of claim 10 under 35 U.S.C. § 103 be withdrawn.

Conclusion

There may be other reasons for patentability for independent and dependent claims, and Applicants do not waive those arguments by failing to assert those arguments here. Applicants view the foregoing reasons as sufficient to establish that the claims are nonobvious, but Applicants expressly reserve the right to make further argument regarding patentability of the claims in future proceedings.

With the above Amendments and Remarks, the Applicants respectfully submit that the application is now in a condition for allowance. If the Examiner is of the opinion that a telephone conference would expedite prosecution of the application, the Examiner is encouraged to contact Applicants' undersigned representative.

Respectfully submitted,

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